PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44*bis*)

Applicant's or agent's file reference 7174.204-WO	**FOR FURTHER ACTION**	See item 4 below
International application No. PCT/EP2006/062301	International filing date *(day/month/year)* 15 May 2006 (15.05.2006)	Priority date *(day/month/year)* 13 May 2005 (13.05.2005)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant NOVO NORDISK A/S		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 11 sheets, including this cover sheet.

   In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☒	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☒	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☒	Box No. VI	Certain documents cited
☒	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44*bis*.3(c) and 93*bis*.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44*bis* .2).

	Date of issuance of this report 13 November 2007 (13.11.2007)
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 82 70	Authorized officer Ellen Moyse e-mail: pt05.pct@wipo.int

Form PCT/IB/373 (January 2004)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43*bis*.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/EP2006/062301	15.05.2006	13.05.2005

International Patent Classification (IPC) or both national classification and IPC
INV. A61M5/168 A61M5/142

Applicant
NOVO NORDISK A/S

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☒ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:	Date of completion of this opinion	Authorized Officer
European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	see form PCT/ISA/210	Ceccarelli, David Telephone No. +49 89 2399-2653

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/EP2006/062301

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed

   ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

      ☐ a sequence listing

      ☐ table(s) related to the sequence listing

   b. format of material:

      ☐ on paper

      ☐ in electronic form

   c. time of filing/furnishing:

      ☐ contained in the international application as filed.

      ☐ filed together with the international application in electronic form.

      ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of

☐ the entire international application

☒ claims Nos. 20-27

because:

☒ the said international application, or the said claims Nos. 20-27 relate to the following subject matter which does not require an international search *(specify)*:

see separate sheet

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed *(specify)*:

☒ no international search report has been established for the whole application or for said claims Nos. 20-27

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

- ☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.
- ☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.
- ☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13*ter*.1(a) or (b).

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See Supplemental Box for further details

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has, within the applicable time limit:

   ☒ paid additional fees

   ☐ paid additional fees under protest and, where applicable, the protest fee

   ☐ paid additional fees under protest but the applicable protest fee was not paid

   ☐ not paid additional fees

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

   ☐ complied with

   ☒ not complied with for the following reasons:

   see separate sheet

4. Consequently, this report has been established in respect of the following parts of the international application:

   ☐ all parts.

   ☒ the parts relating to claims Nos. 1-19,31-34

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	5-8,11-13,15,19,31-34
	No:	Claims	1-4,9-10,14,16-18
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-19,31-34
Industrial applicability (IA)	Yes:	Claims	1-19,31-34
	No:	Claims	

2. Citations and explanations

see separate sheet

Box No. VI Certain documents cited

1. Certain published documents (Rules 43*bis*.1 and 70.10)

   and / or

2. Non-written disclosures (Rules 43*bis*.1 and 70.9)

   see form 210

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

No examination according to Article 33(1) PCT has been be carried out for claims 20-27, as they define methods for treating the human body by therapy or surgery practised on the human body (Rule 67.1(iv) PCT). Arranging a transcutaneous device subcutaneously in a subject is a clear surgical step; expelling fluid drug is clearly a therapeutical step. A computer-implemented surgical or therapeutical method is also considered to have surgical or therapeutical nature.
Moreover no meaningful examination could anyway be carried out for said claims 20-27, since no search report has been established for them (Rule 66.1(e) PCT).

Re Item IV

Lack of unity of invention

The present application lacks unity (Rule 13.1 PCT), as 4 groups of inventions are claimed:

I) **claims 1-19** which essentially define a drug delivery device with a reservoir, an expelling assembly and a controller for detecting two conditions of a transcutaneous device;

II) **claims 28-30**, which essentially define a medical device comprising a transcutaneous device and a controller for detecting two conditions of the transcutaneous device;

III) **claims 31-34**, which essentially define a medical device with a mounting surface for application towards a skin of a subject and a transcutaneous device with a visual marking on its distal portion;

IV) **claims 35-41**, which essentially define a medical device with a mounting surface for application towards a skin of a subject, a first and a second electrode.

The common matter between any two groups of inventions is at most either a medical device with a controller for detecting whether a transcutaneous access device is in a subcutaneous position or not, or a medical device with a transcutaneous device having a mounting surface for application towards the skin of a subject.

Said common matter is clearly not novel over the disclosure of document US2003/0009131 (D1), for example.
See in particular abstract and paragraph 68, for the controller and see pad 28, figure 2b for the transcutaneous device with a mounting surface.

The features of each group which are not common with any of the other groups address different objective technical problems.
Said problems may be regarded as being:

-) a way of insuring appropriate subcutaneous delivery of a drug (drug delivery device with reservoir and expelling assembly of claims 1-19);
-) a way of automatically checking appropriate subcutaneous placement of a transcutaneous device (medical device comprising a transcutaneous device of claims 28-30);
-) a way of facilitating visual inspection of the correct placement of a transcutaneous device (visual marking of claims 31-34);
-) a way of electronically checking the depth of injection with a transcutaneous device (electrodes of claims 35-41).

In more detail, regarding the first and the second groups, claims 1-19 seem to focus on the presence of the reservoir and the expelling assembly, which insure appropriate delivery of a predetermined quantity of drug (content of the reservoir), while claims 28-30 focus on the presence of the transcutaneous device (not necessarily part of claim 1), whereby correct placement of such transcutaneous device is automatically checked.

Therefore, according to Rule 13.2 PCT the requirement of unity is not fulfilled, because there are no common nor corresponding special technical features between any of the four groups.
Since the Applicant has paid additional fees for claims 31-34, claims 1-19 and 31-34 have been examined according to Rule 33(1) PCT.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability;

citations and explanations supporting such statement

1. First invention: claims 1-19.

1.1 Claim 1 is not novel (Article 33(2) PCT) over the disclosure of document D1.
Said document D1 shows a drug delivery device (see figure 11) connected to a transcutaneous access device (14, figure 2a), he drug delivery device comprising a reservoir (23, figure 11), an expelling assembly (25, figure 11) and a controller (see paragraph 68, second sentence) for detecting a first condition representative of the transcutaneous device being arranged in a subcutaneous position and a second condition representative of the transcutaneous device being arranged in a non-subcutaneous position (see paragraph 76, first three sentences), wherein the controller performs an action upon detection of the second condition (see paragraph 3, first two sentences).

1.2 Claims 2-4, 9-10, 14 and 16-18 are also not novel (Article 33(2) PCT) over the disclosure of document D1.
In particular, due to the nature of impedance sensor of document D1 (see paragraph 76), which clearly deprives the current sensor of claims 9-10 of novelty, the controller of document D1 is intrinsically capable of operating according to what claimed in claims 2-4.
As regards the structural features of claims 14 and 16-18, see mounting surface 28, figure 2a, see flexible tube 12, figure 1, and see paragraph 63, first two sentences for the alarm of claims 17-18.

1.3 Claims 5-8, 11-13, 15 and 19 are not considered to be inventive (Article 33(3) PCT) when document D1 is considered as closest prior art.
As regards the nature of the sensor used for detecting the non-subcutaneous position of the transcutaneous device, document D1 clearly teaches that different sensors can be used (see for example paragraphs 63, 64, 68 and 76). Further sensors with particular properties as claimed in claims 5-8 and 11-13 are within the competence of the skilled man based on the teaching of document D1.
A retractable transcutaneous access device is already known in the field (see

document WO2005/039673, figure 24) and is a matter of design (claim 15).
A remote unit with respect to the delivery unit, which indicates a non-subcutaneous position of the transcutaneous device can also only be seen as a matter of design.

2. Second invention: claims 31-34.

2.1 Claim 31 is not inventive (Article 33(3) PCT) when document US 6 485 461 (D2) is considered as closest prior art.
Said document D2 (refer in particular to figures 4-5) discloses a medical device with a mounting surface (13) for application on the skin of a subject, a flexible transcutaneous device (28, see also column 4, lines 16-18) with its distal portion that can be readily identified by the naked eye of a user (through transparent housing 12, see column 4, lines 18-21).
The subject-matter of claim 31 differs from the disclosure of document D2 in that the distal portion of the transcutaneous device comprises a visual marking.
This feature addresses the objective technical problem of preventing or at least immediately recognising unwanted withdrawal of the distal end of the cannula.
Document CA 2 239 457 (D3) shows an intravenous needle with markings at its distal end (see figure 3A and page 2, lines 12-20), addressing the same objective problem (see page 2, lines 4-5).
The skilled man would therefore combine the teachings of documents D2 and D3 and arrive at the subject-matter of claim 31.

2.2 Claims 32-34 are also not inventive (Article 33(3) PCT) over the combination of documents D2 and D3 since their additional features are disclosed in either D2 or D3. See lies 18-24, page 2 of document D3 for the colour marking of claim 32, see lines 18-21 in column 4 of document D2 for the subject-matter of claim 33 and see cannula 28 in figures 4-5 of document D2 for the fact that the transcutaneous device is moveable relative to the mounting surface

Re Item VI

Certain documents cited

Certain published documents

Application No Patent No	Publication date *(day/month/year)*	Filing date *(day/month/year)*	Priority date *(valid claim)* *(day/month/year)*
WO 2006/067217	29.06.2006	22.12.2005	22.12.2004

This document could become important when assessing novelty of claims 1-19 and 31-34 in the regional phase of the present application. In particular see abstract.

Re Item VII
Certain defects in the international application

Documents D1, D2 and D3 are not cited in the description (Rule 5.1(a)(ii) PCT).
The independent claims are not drafted in the two-part form (Rule 6.3(b) PCT).